Remarks/Arguments

Please reconsider the application in view of the above amendments and the following remarks.

Disposition of Claims

Claims 1-29 are pending in the application, and claims 1-29 are rejected.

Oath/Declaration

The Examiner stated that the oath or declaration is defective. In response, a new oath is submitted herewith, in compliance with 37 C.F.R. 1.67(a), identifying this application by application number and filing date, and containing the citizenship of the inventor.

Rejections under 35 USC § 112

Claims 1, 2, 4-10, 12-16 and 18-28 stand rejected under 35 USC § 112, 1st Paragraph for failing to comply with the enablement requirement. Applicant respectfully traverses.

The Examiner states that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make/use the invention. Examiner further states that polyester fabric could (theoretically) be a "sample", that one of ordinary skill in the art would not know how to extract RNA from inorganic polyester material, and that the specification and claims do not teach how to extract RNA from these types of "samples".

The Applicant respectfully disagrees. The specification describes the types of "samples" that would be used with the present invention, in numerous places, as specified below.

1. Applicant provides a specific examples of samples at page 19, lines 1-4, for example. See current specification, page 19, lines 1-4. Thus, specific, relevant types of samples for use with the present invention are directly described. Therefore, Applicant believes the use of "sample" in the claims is enabled as it is described in the specification in the context of the invention.
2. Further, the general field of the type of assay being improved by the present invention is described in the specification wherein pharmaceutical and biotechnological assays are discussed. See current specification, page 4, lines 3-12. Thus, Applicant believes that the general field of a biotechnological assay is

established and those of ordinary skill in the are would understand the term "sample" and how a "sample" would be used and what would be a relevant "sample" for this type of assay.

3. Additionally, the specification describes drug screening and screening chemical entities in a biologically relevant environment. See current specification, page 5, lines 1-8. Again, this establishes the field of art, and type of assay of the invention, and thus Applicant believes the type of relevant sample that would be known to one of skill in the art.
4. The specification additionally describes DNA micro arrays. See current specification, page 6. Applicant believes that from the specification, one of ordinary skill in this art would understand what would be a relevant sample for such assays.
5. The specification describes relevant samples for this type of assay as nucleic acids, DNA and RNA. See current specification, page 7, lines 7-16.
6. Finally, the specification specifically states that all the technical and scientific terms used in the application have the same meaning as commonly understood by one of ordinary skill in the art. See current specification, page 14, lines 8-12.

Thus, Applicant believes he has shown that the general field of the assay methods and systems of the present invention have been established by the specification and one of ordinary skill in the art would understand what is meant by the claim term "sample", and one of ordinary skill in that art would understand that a possible relevant "sample" does not include an inorganic fabric.

In addition, neither of the patents cited by the Examiner in the 102 and 103 rejections defines the word "sample" with respect to what it does not include. A relevant sample would be assumed to be known in the art. For example, US Patent 5,874,219 to Rava et al. simply claims a "test sample". There is no need to explain to one of ordinary skill in the art of biological assays that a "sample" would have to include some sort of biological material in order for the word "sample" to be enabling. One of ordinary skill in the art would know the usual meaning of "sample" and perhaps, using Examiner's example, a forensic scientist would know that a

"sample" for a biological assay would be, say, the blood found on a polyester fabric as opposed to the actual fabric itself.

Enablement, as Examiner points out, is determined in context, relative to one of skill in the relevant art. Based on the description and discussion of the relevant art, and Applicant's specific examples of some relevant sources of samples (See discussed above, See also current specification, page 19), Applicant believes the specification enables one of ordinary skill in the art to know what a sample would be and would know how to extract RNA from a relevant biological sample. Additionally, as terms "sample" and "biological sample" used in the claims as amended is enabling and supported by the specification. For these reasons, Applicant respectfully requests that the rejection under 35 U.S.C. 112, 1st paragraph, be withdrawn.

Claims 1-14, 20, 21, 23, 24, 26, 27 and 29 stand rejected under 35 USC § 112, 2nd Paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention.

Examiner states that the preambles of independent claims 1, 9, and 29 recite that the invention is a method and system, yet examiner feels none of the rejected claims includes limitations drawn to a system. In response, Applicant has amended claims 1, 9, and 29 to overcome this rejection.

The claims have been amended so that there are now separate method claims and separate system claims. Claims 1, 9, and 29 have been amended so that, in the preamble, they are drawn only to methods. New, separate system claims 33-36 have been added. Claim 29 stands rejected under 35 USC § 112, 2nd Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Examiner states that it is unclear what in the body of the claim are the samples referred to in the preamble.

In response, Applicant amends claim 29, and amended claim 29 is supported by the specification at page 19 that the labeled cDNA are the samples.

Thus, Applicant believes the amendments are sufficient to place the claims in condition for allowance, and Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. 112, 2nd paragraph.

Rejections under 35 USC § 102(b)

Claim 29 stands rejected under 35 USC § 102(b) as being anticipated by Rava et al. Applicant respectfully traverses.

Examiner asserts that Rava et al. teach a method and system for multiple parallel analysis of samples, having all the elements of Applicant's invention. Applicant respectfully disagrees. Applicant claims methods and systems performed directly on a glass bottom microtiter plate platform. Rava does not. Rava "pre-deposit" their arrays on preferably flat glass or silica, but then must construct liquid-impermeable separation between the arrays, or cut the substrate apart into individual chips and then put a chip containing an array (on the glass or silica substrate) into the well of a microtiter plate. Applicant's invention, as claimed, deposits arrays directly onto the inner bottom glass surface of a glass bottom microtiter plate. Rava specifically state that the body of their biological chip plate contemplates a variety of polymers already used for microtiter plates. See Rava, col. 8, line 57-67. Their microtiter plates, when used, do not have glass bottoms.

Therefore, Applicant's invention contains elements not claimed or disclosed by Rava, namely, glass bottom microtiter plate platforms. Applicant's invention also contains method steps not claimed or disclosed by Rava, namely, depositing arrays directly in and on glass bottom microtiter plate platforms. Thus, because every element of Applicant's invention is not disclosed by Rava et al., the rejection has been overcome and Applicant respectfully requests withdrawal of the rejection.

Rejections under 35 USC § 103(a)

Claims 1-28 stand rejected under 35 USC § 103(a) as being unpatentable over Lockhart et al. in view of Rava et al. Applicant respectfully traverses.

Examiner asserts that Lockhart teaches a method and system of analyzing samples by probe arrays, but does not teach those in the context of a multi-well microtiter plate platform. Examiner asserts that Rava teaches biological chip array technology in a multi-well microtiter plate platform and that it would have been obvious to combine the biological chip array technology of Rava with the biological array methods and systems of Lockhart et al.

Applicant respectfully disagrees. Rava et al. uses a different physical structure for their assays than the Applicant. Also, Applicant can perform, and claims, single label analysis of multiple samples, which saves time and expense over current methods. Applicant also can

use two labels and process two samples in one well, on one array, contrary to the current methods which require a control and one sample for each array. The cited references simply do not teach or suggest Applicant's simpler assays and platforms that can process far more samples at once than currently possible. In addition, the cited references do not teach the control methods and system of Applicant's invention in which a single control can be used for each type of array or each label, control or dose curves can be performed, or two controls can be used if two samples with different labels are being processed in each well. Applicant's invention eliminates the need for a two label system with a control and one sample for each array, thus vastly improving the reproducibility, accuracy of such assays, and allowing many more samples to be processed than is possible with current methods.

First, Rava teaches a different structural and physical method and platform than Applicant. As defined by Rava a "biological chip" is: "A substrate having a surface to which one or more arrays of probes is attached. The substrate can be, merely by way of example, silicon or glass and can have a thickness of a glass microscope slide or glass coverslip." The term also refers to a probe array and the substrate to which it is attached that form part of a "wafer". A "wafer" is defined as: "A substrate having a surface to which a plurality of probe arrays are attached. On a wafer, the arrays are physically separated by a distance of at least about a millimeter, so that individual chips can be made by dicing a wafer or otherwise physically separating the wafer into units having a probe array." And a "biological chip plate" is: "A device having an array of biological chips in which the probe array of each chip is separated from the probe array of other chips by a physical barrier resistant to the passage of liquids and forming an area or space referred to as a "test well", capable of containing liquids in contact with the probe array."

Also, as defined by Rava, in the methods of the invention, a biological chip plate is provided having a plurality of test wells and each test well includes a biological chip. A chip can be seen in well in Figure 3 of the Rava reference.

Rava disclose three preferred ways of making their biological chip plates, each requiring "pre-deposition" of probe arrays before the chip plates can be made.

The first method is a two-part structure wherein arrays are deposited on a wafer and a top body of the plate having channels is positioned on the wafer, such that the channels for the walls of wells and each channel surrounds and encloses a probe array on the wafer.

The second method uses a plate with pre-formed wells, for example a typical microtiter plate. The arrays are deposited on the wafer that is then cut apart so each array is physically separate, forming tiny chips. Then a single chip is placed in each pre-formed well where an assay is to be performed.

The third method deposits the arrays onto a wafer that has physical means for separating liquid, such as wax, tape, or other hydrophobic materials in the spaces between the arrays, forming cells that act as test wells.

All of Rava's arrays are deposited first on a thin wafer, then either separated by a frame having channels, cut apart and deposited in wells, or separated by some sort of liquid-impermeable material. Thus, all of Rava's assays require at least three steps: 1. depositing arrays on a wafer; 2. treating the wafer in some way (adding a frame, cutting the wafer apart, or separating by liquid-impermeable material), and 3. finally adding the test sample.

Nowhere does Rava disclose simply depositing an array directly, with no pre-preparation, onto the glass bottom of a glass bottom multi-well microtiter plate assay platform.

Applicant's invention does not require "pre-deposition" or "pre-formation" of an array on a wafer. Applicant's method and system, as claimed, simply deposit arrays directly onto the bottom glass surface of the test wells. Thus, Applicant's invention reduces the time required to prepare and perform such assays, and by eliminating steps, reduces the chances for error in the assay process.

Rava specifically defines in detail a biological chip as being on or part of a wafer, and require the arrays to be deposited on such wafers. They go into great detail about how and on what material and structure arrays can be formed and there is no mention at all that arrays could be deposited simply and directly in glass bottom wells of a microtiter plate.

Thus, there is no teaching or suggestion whatsoever, that arrays can even possibly be deposited directly into glass bottom microtiter plate wells, directly onto the glass material of the microtiter plate platform.

Therefore, regardless of what types of assays Lockhart teaches, even if they were combined with the teachings of Rava, Applicant's invention would not result. Rava et al. are very specific about how their wafers, biological chips, and chip plates are formed and defined and they simply do not contemplate, teach or disclose Applicant's much simpler methods and system. Examiner, in the Official Action, quotes where Rava et al. specifically say the assays are performed on biological chips, not directly in/on a microtiter plate. Examiner states that Rava. teaches: "This invention provides automated methods for concurrently processing multiple biological chip assay...Because they allow much higher throughput of test samples, these methods greatly improve the efficiency of performing assays on biological chips (col. 4, lines 33-40)." See Office action, page 7. Applicant's invention does not perform assays on biological chips.

While Lockhart discusses various types of assay labels, detection methods, analysis methods and assay controls, as Examiner notes, there is no disclosure regarding how or on what the assay arrays are deposited, immobilized, prepared or performed. Thus, such teaching regarding how arrays are prepared would have to come from some other reference. Examiner cites Rava. However, as pointed out above, while Rava discloses various methods and systems for preparing arrays and assaying samples using those arrays, Rava does not teach or suggest, anywhere, Applicant's much simpler methods and systems for preparing arrays and performing various assays directly on microtiter plate platforms.

Further, the Office action fails to show that there is any motivation sounds in Rava or in any other prior art to modify Rava to include features taught in Lockhart. Because there is no motivation to modify Rava in the manner suggested in the Office action, and even if the references were combined, the resultant method would not be the same as the present invention, applicant submits that claims 1-28 would not have been obvious and requests that the rejection under 35 U.S.C. 103 be withdrawn.

Conclusion

The claims have been shown to be allowable over the prior art. No new matter has been added. Applicant believes that this paper is responsive to each and every ground of rejection cited by the Examiner in the Action dated December 30, 2003, and respectfully requests

favorable action in this application. The Examiner is invited to telephone the undersigned, applicant's attorney of record, to facilitate advancement of the present application.

The applicant herewith petitions the Commissioner of Patents and Trademarks to extend the time for reply to the Office action dated December 30, 2003 for two months. Please charge deposit account number 04-0932 (Reference Number 12951/60688), in the amount of $210.00 to cover the cost of the extension. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

Respectfully submitted,

Date: 05.28.04

By: _____
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